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ABSTRACT

This pamphlet offers a series of self-assessment guidelines and questions which college and university officials can use to help determine the extent to which they are taking the appropriate measures to reasonably protect the institution's interests, maximize the economic value of technical discoveries made by faculty, and still maintain an appropriate separation between academia and the commercial world. After a brief description of the relationship between universities and technology transfer, activities leading to the commercialization of faculty members' discoveries, and a review of risk assessment in technology transfer, a section on the nature of possible risks follows. Those risks include fiduciary liability, liability arising from negligent conduct (simple negligence and product liability), and contractual liability. The following section discusses how institutions can control those risks by either managing commercialization activities through the structure of the activities or by structuring research and development foundations, commercial spin-offs, and related activities. There follows a discussion of the importance of consistent application of appropriate policies with a checklist for self assessment in this area. A final section examines several models in the context of risk management including an evaluation of the effects of the particular structure on a set of elements that are central to commercialization efforts. (JB)

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Technology Transfer and Risk Management

MICHAEL B. GOLDSTEIN

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National Association of College and University Attorneys

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Technology Transfer and Risk Management

Introduction

In recent years, an increasing number of colleges and universities have become involved in what is broadly defined as "technology transfer:" activities leading to the commercialization of discoveries made by faculty members. Many other institutions, recognizing the potential economic value of faculty discoveries, are considering embarking on such efforts. A restraining force, however, has been an uncertainty over the nature and magnitude of the risks faced by institutions that engage in commercialization of faculty research. Compounding this uncertainty has been the question of whether there exists a reasonable way to assess those risks so that an institution, its administration and its governing board might make a prudent decision as to whether it is even in the institution's best interests to proceed with such a venture and, if so, under what circumstances. Thus, one of the critical questions which an institution must answer is whether the benefits of institutional involvement in technology transfer—that is, the commercialization of the fruits of faculty research—are worth the potential risks to the institution and its personnel.

The answer is twofold. First, with precious few exceptions, institutions no longer have a choice whether or not to be involved in technology transfer. While there are certainly significant options regarding the *manner* through which such transfers occur, and therefore regarding the role of the institution itself, virtually every college and university has among its faculty men and women with the capability of creating discoveries with commercial value. Unless the institution is to waive its rights to such work (which in itself does not necessarily protect the institution against loss), technology transfer is a fact of life for American higher education.

Second, institutions can no longer *afford* to sidestep the issue of commercialization of

faculty discoveries. The potential economic value of such efforts cannot be ignored in an era when every resource must be carefully conserved. Pressures to constrain tuition and hold down government spending are conspiring to create an atmosphere in which an institution must look to every opportunity to generate revenues to support its mission. The commercialization of faculty discoveries represents the *potential* (and one must emphasize that it is an elusive potential) for significant revenue enhancement.

Given these parameters, how can an institution prudently protect its interests, and those of its faculty, while participating in technology transfer to the extent and in the manner it deems appropriate? This pamphlet offers a series of self-assessment guidelines and questions which college and university officials can use to help determine the extent to which their institution is taking the appropriate measures to reasonably protect its interests, maximize the economic value of the discoveries *and* still maintain an appropriate separation between academia and the commercial world.

"Informed understanding" is central to this analysis. Much of the resistance to institutional involvement in commercialization activities that is common among faculty, administrators or trustees comes from a rather natural wariness of the unknown. The consequences of becoming involved with the commercial sector, except in a very few time-honored ways, are poorly understood, even with regard to the potential benefits. Equally vague is the true nature of the oft-cited "down side risks." The result is a two-edged sword: a reluctance to engage in potentially rewarding activities *and* an *increased* risk of loss arising out of a failure to exercise due care. Since it is the *unknown* risks that are the most dangerous, this pamphlet will offer guidance for making informed—rather than blind—judgments on commercialization activities.

It is also painfully clear that every time a technology transfer program suffers a significant loss, a chill is cast over the entire effort of academia to move discoveries into the stream

of commerce. It is only through knowledge of the risks and preparation for their control or avoidance that the enormous potential of our institutions can be brought to bear in ways that will best benefit them, their faculty and society as a whole.

Universities and Technology Transfer

Historically, universities have been a fertile breeding ground for ideas and discoveries that, over time, have been the basis for commercially successful products and processes. This transfer of technology from academia to commerce has taken place through a variety of vehicles, ranging from the disclosure of discoveries in the scholarly literature, to patents and licensing programs often connected with research support, to active partnership in the commercialization process.

The assumption of a more active role on the part of institutions has enabled them to better control the manner in which discoveries are developed and, more to the point, to afford them—and their faculty—a more equitable share of the economic value of the discoveries. Joint ventures, commercialization spin-offs and incubators have all had the salutary effect of providing mechanisms that allow institutions to garner significant revenues, obtain costly research instrumentation and, perhaps most important, encourage productive faculty members to remain in academia without having to forego attractive economic opportunities. Even licensing programs have become far more sophisticated, with institutions taking a considerably more aggressive stance in negotiating agreements for the use of their intellectual property.

There are, however, fundamental differences between academic research and commercial activity. The former seeks answers—truths, if you will—for their own sake. The utilization and commercial exploitation of those answers is the responsibility of others. The users of the research may profit from it but, in doing so, they also bear the risks, first that it may not prove economically viable and, second that it may not be altogether beneficial.

Unlike universities, however, commercial ventures are in large measure organized for the express purpose of dealing with such risks, be it by limiting the liability of investors, shifting the potential impact of losses through insurance or indemnification and, most important, by a general understanding among the participants in the venture that the risk of loss does indeed exist. In contrast, the term "risk adverse" quite accurately and properly describes virtually all academic institutions. Financial ruin, occasioned by imprudent involvement in commercial activities, is obviously a far more serious loss when the victim is a college, since the primary functions of instruction and research can be fatally damaged by an ancillary activity: the venture. No reasonable trustee, administrator or faculty member could abide by such an outcome.

Thus, as universities become more involved with commercialization activities, there must be clear recognition of the potential risks as well as the potential benefits. Universities must act aggressively to maximize the return to the institution arising out of the intellectual property created by its faculty, and they need to create mechanisms that sufficiently reward productive faculty members so that they are more likely to remain at the institution rather than cross over to the for-profit sector. Therefore, an additional purpose of this pamphlet is to give institutional managers the insight they need to strike the delicate balance between the risks and the benefits of technology transfer.

Risk Assessment in Technology Transfer

There are some who would argue that controlling risks associated with the commercialization of discoveries is a problem primarily for the large research universities, and that other institutions ought not to have to concern themselves with its complexities. While it is certainly the case that the great research institutions are very substantial generators of the discoveries that ultimately move into the marketplace, it is both incorrect and unwise to assume that

this is not also an important issue for other institutions.

The point is not whether an educational institution is *presently* involved in a *significant volume* of research commercialization or technology transfer activity, but whether it is, or is at all likely to be in the future, involved in *any* such activity. The mere possibility, if not probability, of commercializable research activity ought to be sufficient to encourage all institutions to undergo the process of self-assessment suggested in this pamphlet. Indeed, it is just the institutions *without* a "significant" volume of potentially commercializable research that may face the greatest risk of loss. While one might have some confidence that the major research universities are reasonably sophisticated in their management of technology transfer and commercialization, the same assumption is manifestly *not* correct for institutions with a small volume of such activities. Yet a single researcher working at a smaller institution may create a discovery as a valuable—and as potentially risk-laden—as anything emerging from a major research university.

Nature of the Risks

The risks related to commercialization activities arise in two broad categories: economic loss to those who have invested in the activity and harm to those affected by it. Either may result in a risk of financial loss to the institution and even, under particular circumstances, liability assessed against its officers and trustees.

Risks arising out of losses by investors, while more likely to do so, are also more easily defined and, fortunately, relatively controllable through a variety of methods, primarily organizational. Risks arising out of harm to third parties, on the other hand, are extremely difficult to predict, complex to protect against and potentially devastating in terms of the consequences. Common examples of the latter kind of losses are damages occurring as a result of a defect in a product or injuries sus-

tained as a result of the operations of a commercialization activity.

Other forms of liability that may also accompany technology transfer activities include contractual violations (particularly alleging conflicts of interest but also including disputes arising out of the terms of an investigator's contract of employment) and violations of intellectual property rights. In particular, allegations of conflict of interest have become intimately connected with technology transfer, in large measure because it is so easy for an investigator to find him or herself compromised between the ill-defined interests of the institution and those of a commercial entity. Likewise, intellectual property violations often arise out of a lack of knowledge of prior rights (notably prior research support) rather than any party's intention to infringe the rights of another.

Fiduciary Liability—Protecting the Investment

Investors in any commercial undertaking, by definition, stand to lose all of their investment if the undertaking is a failure. If the investor is so unwise as not to limit his or her liability, personal fortunes may be at risk as well. In the commercialization of discoveries, it is painfully common that the costs of developing a promising discovery are never recovered through its commercial sales, if indeed the discovery ever makes it to the marketplace at all. In such a case the funds invested in the commercialization of the discovery may simply be gone without any hope of recovery. That kind of loss is readily measurable: it is simply the value of the direct investment in the commercialization venture. In the case of an institution whose contribution to the equity of the commercial entity is the discovery itself, the failure of the invention to be commercially viable may not bear with it any direct financial loss—although if commercialization would have been possible through a different approach or with different partners, there will be lost *opportunity* costs.

The greater risk occurs when *other* investors—if they believe their interests were not

properly protected by those running the venture—seek to recover *their* losses. This is a considerably more substantial risk than that arising from the loss of direct investment, since the value of the loss may be the *aggregate* amount invested in the venture or, if it can be proven that, as a result of the negligence of management, the investor lost measurable profits. If the structure of the enterprise is such that the institution or its surrogate could be deemed to have a governance role (as that term is defined in commercial law, not academia) and, if it has not taken steps to limit its own liability, the financial risk can in fact be very substantial.

Liability Arising Out of Negligent Conduct

There are two distinct types of liability arising out of negligence. The first, *simple negligence*, occurs in the process of the technology transfer, and most typically involves harm to persons or damage to property arising out of the conduct of the commercialization operation; the second, *product liability*, results from the use of the product arising out of the commercialization activity.

1. Simple Negligence. The most straightforward example of simple negligence is that of the visitor who slips and falls on a grease spill in the laboratory of a spin-off entity. More complex examples are illnesses caused by exposure to dangerous chemicals or damage to equipment or facilities owned by third parties. The worst case scenario might involve the release of toxic gases that affect neighboring residents. In such cases, the issue of who is at fault tends to be relatively straightforward (although more complex factual situations often make for more complex determinations of fault), and the identity of the injured parties is typically self-evident.

Not necessarily as clear is the question of ultimate liability. Consider, for example, an injury that occurs on the premises of a start-up company which is wholly owned by an institution, either directly or through an intermedi-

ary. If the start-up company is operating out of premises that are leased from the institution or, if it is subject to management control by the institution or its intermediary *and*, as is commonly the case, the start-up company has very limited resources of its own, it would not be difficult to find a situation where liability is determined to extend back to the institution itself. The elements contributing to such a risk, and the ways to control it, are discussed in subsequent sections.

2. Product Liability. The second risk, product liability, arises when a commercial product causes harm as a result of an inherent defect that was known—or should have been known—by those who either market it or were involved in the process that resulted in its being offered in commerce. Product liability is a far more complex legal concept than is simple negligence, primarily because it manifests itself only *after* the discovery has become a commercial product and has been distributed in the marketplace. The complexity is also the result of the fact that a product liability claim must contain the following elements:

1. Evidence that the product caused the harm;
2. Evidence that the harm was caused by the conduct of the defendant (or the defendant's agent, e.g., the investigator);
3. Evidence that the defendant was negligent in allowing the harm to occur; and
4. Evidence that the plaintiff was actually harmed by the defect in the product.

The most serious problem with losses arising from the use of any product is the inherent difficulty of predicting their "behavior." Obviously, no one would knowingly bring a product to market that, years later, would cause financial loss, injury or death to those who use it. But that is of course what has happened numerous times: the law does not require any finding of malignant intent for liability to be imposed. The risk of such liability—which can be of monumental size, as demonstrated by the Dalkon Shield case—looms over every company engaged in bringing new products to market.

When a university becomes *in any way* involved in commercialization, even if only through the licensing of its discoveries, there is a risk that a product derived from the discovery will cause harm, and the institution will be required to accept responsibility for at least a portion of that harm. Since the magnitude of that risk may be sufficient to bankrupt even the most financially stable institution, it is essential that great care be taken in embarking upon such activities. Of utmost importance are the measures taken by the institution to insulate itself and its personnel from the risks of commercialization activities. The ways an institution can seek to protect itself are discussed in a subsequent section.

Contractual Liability

A third source of financial risk arises out of violations of contractual rights. There are many possible sources of such risk. For example:

1. A faculty member may claim that he or she is entitled to a different share of the financial benefits arising out of the commercialization of his or her discovery than the institution otherwise believes to be the case.
2. A partner in a commercial venture may claim that the institution failed to deliver on what it was contractually obligated to provide. In many cases, this means that the institution failed to provide a discovery that does not infringe on another entity's patent or copyright.
3. A faculty member may contract with a commercial entity to develop his or her discovery, ostensibly outside of his or her employment with the institution. Whether the work actually was performed separate from his or her institutional responsibilities may result in a dispute between the institution and the entity over who owns the discovery.
4. An institution may accept a sponsored research agreement that gives the sponsor protection against premature disclosure, but the faculty investigator may nonetheless release information that damages or destroys the patentability of the discovery.

Contractual liability is different from liability rising out of negligent conduct in that the institution could be acting in good faith and still violate a contractual obligation; that is, infringe on the *contractual* rights of another party. The case of a faculty member who claims that he or she—rather than the institution—"owns" a discovery is an excellent example. Typically, the faculty member will argue that the discovery was created apart from his or her employment by the institution, raising a complex set of factual as well as legal issues. However, the conduct of officials of the institution can readily exacerbate this particular type of problem.

For example, a faculty member may claim that his or her actions transferring certain of the rights in a discovery to a commercial entity were expressly authorized by a university official, despite contrary provisions in the institution's published policies. The issues that a court will address are not simply whether the university official in fact authorized the faculty member to act as he did, but whether the official *either* had the *actual* authority to so act *or reasonably appeared* to have that authority. Even if the university official did not have the actual power to modify the regulations governing control of discoveries, if the faculty member acted in a *reasonable belief* that the official had that authority, a court may sustain his or her action.

Likewise, as described above, while the premature disclosure of a discovery may have been without any formal institutional authorization or involvement, the institution would nonetheless generally be held responsible for the violation since, as a matter of law, the institution is responsible for the conduct of its personnel (even its faculty!).

Controlling Risk

Risks rising out of commercialization activities may be controlled in two key ways:

1. The commercialization activity can be *structured* so as to limit (or at least minimize) the risk of loss to the parent institution.

This can best be accomplished through specific mechanisms:

a. An agreement, such as a license, which transfers certain rights in a discovery without any warranties or representations;
b. An investment with limited recourse (such as a limited partnership or the ownership of stock); or
c. The isolation of the commercial activity in a legally separate entity.

2. The burden of losses which do arise and which otherwise could be attributed to the institution (or to a commercialization entity under its control) can be shifted to another party. The most common vehicles for accomplishing this are indemnification agreements and the most common form of risk shifting, commercial insurance.

The manner through which an institution engages in commercialization activities has a great deal to do with its ability to control the risks arising out of those efforts. The structural issues begin well before the terms of a licensing agreement or joint venture are even developed. In fact, they start with the degree to which the institution exercises control over the *entirety* of the commercialization process, beginning with the conduct of the investigators and their relationship with and responsibilities to their institution.

General Management of Commercialization Activities

The general management of commercialization activities is the area most often ignored by institutions with limited amounts of research, primarily because it is commonly believed that the research is unlikely to result in commercial activity. The prevalent attitude is that the institution need not invest any resources (human, as well as financial) *until* after a technology transfer project emerges. Unfortunately, that may be too late. The absence of any central coordination is likely to result not only in disparate institutional policies and their uneven enforcement, but it may very likely increase the chances that individual investigators will go

off on their own and create their own technology transfer arrangements, often unaware of the fact that such arrangements may in fact end up binding the institution as well as themselves.

In an effort to avoid institutional liability and achieve effective management control, colleges and universities should consider the following measures:

1. Establish an institution-wide office with responsibility for the general oversight of *all* commercialization activities.
2. Ensure that all agreements for commercialization, including sponsored research resulting in the transfer of any rights in discoveries, are reviewed and approved by legal counsel.
3. Ensure that the policies governing the conduct of faculty and other professional personnel:
   a. adequately address the rights of faculty to discoveries in which they participate; and
   b. provide standards for, and require disclosure of, faculty interests in any commercial ventures that are in any way related to their institutional research activities.
4. Evaluate each discovery to ascertain its patentability or amenability to protection under the copyright laws, and provide an expeditious and professionally managed patent and copyright process.
5. Evaluate each discovery to determine the nature of potential product liability risks.
6. Thoroughly review the qualifications of each potential commercial participant, and determine the adequacy of each one's financial, managerial and technical capacity.

The Structuring of Research and Development Foundations, Commercialization Spin-Offs, and Other Related Entities

Institutional chief executives and governing boards are divided fairly equally regarding whether colleges and universities should create research and development foundations, spin-

off companies, or other forms of related entities to facilitate the commercialization of discoveries while minimizing risk to the institution. For example, a well-constructed commercialization subsidiary can give an institution a reasonable level of protection from certain types of losses and, at the same time, enable it to secure new sources of support for its research activities. However, the mere creation of another corporation does *not*, in itself, necessarily give the institution any additional protection. Indeed, if the filing of corporate papers for a spin-off entity is enough to satisfy a governing board's concern with the structuring of the institution's commercialization activities, then such an action can actually *increase* the risks faced by the institution. Finally, the best intentioned separation of responsibilities between an institution and an independently created entity can come to naught if that separation is breached in certain key ways.

Regardless of whether an institution employs an existing or a new entity for commercialization activities, there is a series of questions that should be answered to allow the institution to assess its risks responsibly:

1. Is there a written opinion of counsel stating that the entity, under applicable law, has an entirely separate legal existence?
2. Is the governance of the entity distinguishable from that of the institution?

   Within the context of the governance of the entity, several supplemental issues should be considered in reviewing the composition and duties of the governing board of the *entity*, and in assessing the degree of legal independence of the *directors*. These include:

   a. Who selects the board of directors of the entity?
   b. To what extent must an employee of the institution who sits on the board of the entity report to the institution regarding his board activities and to what extent are his or her activities actually controlled by his or her superiors?
   c. To what extent are the activities and decisions of the board of the entity

directed by the institution?

d. To what extent do the activities of the board of the entity further the mission of the institution?

e. To what extent can a director of the entity portray himself or herself as acting with the actual or apparent authority of the institution?

f. To what extent do the directors of the entity deviate or depart from the mission or best interests of the *entity* to serve the purposes of the *institution*?

3. Are the operational relationships between the institution and the subsidiary so intertwined as to lead a court to ignore the intended separation?

The following elements, taken together, in whole or in part, could weaken a claim of separate identity:

a. The institution pays all or a substantial part of the salaries of the personnel of the entity.

b. The institution pays all or a substantial part of the expenses of the entity.

c. The institution owns the facilities or grounds used by the entity.

d. The institution represents, either expressly or implicitly, that it would stand behind the entity in the performance of the latter's contracts.

e. The institution owns all or substantially all of the equity of the entity.

f. All or most of the officers, directors or both of the entity are the same as those of the institution.

g. The entity is financed in whole or substantial part by the institution.

h. The entity fails to maintain the formalities of a separate corporate existence (e.g. independent meetings of directors, separate books, etc.).

i. The logos and other marks of the entity are the same as or substantially similar to those of the institution.

j. The public is unaware of the separate corporate existence of the entity.

4. If a major part of the *ministerial* management of the entity is to be contracted back to the institution, is the agreement providing for such a transfer explicit in the delineation of delegated responsibilities?
5. Is the institution's ownership interest in a commercialization entity passive?
6. Is the entity required to disclose to the institution the nature of all of its relationships with other entities and individuals, including all subcontracts and assignments that relate to the commercialization of the discoveries?

Policies for Avoiding Risk

Independent structures, such as research and development foundations, commercialization spin-offs, and other related entities can help minimize the likelihood of the parent institution being found liable for losses arising out of the commercialization activity. But it is only through the development and consistent application of appropriate policies that such risks can adequately be controlled. The following checklist may assist an institution in either assessing the viability of its existing policies or in formulating new policies:

1. Does the institution have written institution-wide policies for all sponsored Research and Development and commercialization activities which set forth standards for risk sharing?
   a. Are all investigators provided with a copy of such policies?
2. Are indemnification agreements supported by an objective professional evaluation of the indemnifying entity's ability to respond to the maximum potential liability?
3. Are the institution, as well as its commercialization entity and any related intermediate entities, named insureds on all insurance policies obtained by a commercial partner that in any way relate to the subject of the relationship between the parties?
   a. Are copies of the certificates of insurance provided to the institution and reviewed for sufficiency by the institution's risk manager and/or legal counsel?

4. Is each discovery professionally evaluated as to the nature of potential risks, including product liability?
5. Do agreements transferring rights to other entities, including licenses, expressly exclude warranties of marketability or fitness for use?
6. If the discovery is not already patented, do rights transfer agreements expressly exclude any warranty of patentability?

While the promulgation of appropriate policies is important, they serve no purpose if they are not properly and consistently implemented. All of the best policies cannot protect an institution against liability if they are ignored or circumvented, either intentionally or because someone was unaware of their importance and rationale.

Technology Transfer Models

The various methods used by colleges and universities to market their discoveries have undergone considerable evolution in recent years. This section examines several models in the context of risk management. Each example includes an evaluation of the effects of the particular structure on a set of elements that are central to commercialization efforts. The first three of these elements concern the degree to which the structure can benefit the institution and the investigator. The fourth considers the difficulty of administering the structure, while the last two deal with the degree to which the structure facilitates control and limits potential risks. As applied to each model, the six elements are rated on a scale from "Very High" to "Very Low." In some cases, the rating is stated as either "varies" or within a range, indicating that the specifics of the particular structure can affect the rating of the element. The six elements, and the interpretation of the associated ratings, are:

1. **Commercialization flexibility**, defined as the degree to which the parties are free to make use of different structures and strategies (ranging from licensing to joint ventures) to achieve commercialization.

- *High* indicates that the structure allows a very significant degree of freedom in terms of the kinds of relationships that can be used to bring a discovery to the marketplace.
- *Low* indicates that the structure itself constrains such flexibility.

2. **Benefit to the institution**, taking into account the potential return to the institution of a share of the value of the discovery, and assuming that the discovery is of commercial value.
   - *High* indicates that the structure affords the institution the opportunity for maximum benefit from the commercial value of the discovery.
   - *Low* indicates that the structure impedes institutional recovery of substantial economic benefit.
3. **Benefit to the investigator**, taking into account the potential return to the investigator of a share of the value of the discovery.
   - *High* indicates that the structure may afford the investigator a substantial share of the economic value of the discovery.
   - *Low* indicates that the structure may impede the ability of the investigator to benefit from the economic value of the discovery.
4. **Administrative burden**, taking into account the extent to which the institution must devote overhead resources to the management of the commercialization process.
   - *High* indicates that the administration of the structure requires substantial *additional* overhead resources, beyond those normally associated with the management of the institution.
   - *Low* indicates that the structure can be administered without substantial overhead resources.
5. **Institutional risk control**, defined as the degree to which the institution can act to define and set limits upon its exposure. The former may be more easily accomplished than the latter.

- *High* indicates that the risks to the institution usually associated with the structure can be reasonably well defined and controlled.
- *Low* indicates either that the risks are difficult to define or, even if definable, are difficult to control.

6. **Institutional risk exposure**, defined as the potential exposure of the institution itself to losses arising out of the commercialization of the discovery. This is further divided into two categories: *fiduciary liability* and *liability arising from negligent conduct.*
   - *High* indicates that the structure is ineffective in deflecting liability from the institution.
   - *Low* indicates that the structure is relatively effective in deflecting liability from the institution.

Faculty Ownership of Rights and Control of Commercialization

There are several generic models, each with a number of principal subsets. The simplest (although by no means the best) way for an institution to treat the commercialization of faculty discoveries is the same way it treats the authoring of books and articles. Under the statutes of a vast majority of American institutions, faculty authors retain the copyright to their writings, and are free to negotiate their own business agreements with publishers. Commonly, the institution does not retain any residual rights in the work and does not receive any direct benefit from its publication, except where the authoring involved a very specialized use of institutional resources.

Characteristics:
Commercialization flexibility: High, but limited
Benefit to the institution: Very low
Benefit to the investigator: Varies from very low to very high
Administrative burden: Very low
Institutional risk control: Very low
Institutional risk exposure:
  Fiduciary liability: Very high
  Product liability: Very high

Licensing of Discoveries

By far the most common way institutions are able to transfer discoveries into the marketplace is through the negotiation of a license with a commercial entity, which will then complete the discovery's development and produce and market the resulting product. Such licensing activities are carried out through several structural models, each of which has different risk assessment attributes:

1. **Direct licensing by the institution.** Under this model, the institution carries out its own licensing program, entering directly into agreements with commercial entities.

Characteristics:
Commercialization flexibility: Low
Benefit to the institution: Varies
Benefit to the investigator: Varies from very low to moderate
Administrative burden: High
Institutional risk control: High
Institutional exposure:
Fiduciary liability: Low
Product liability: Moderate

2. **Licensing of Discoveries Through an Outside Licensing Entity.** Under this model, the institution grants an independent entity the right of first refusal to its discoveries. The entity, which commonly has as clients a large number of institutions, in turn seeks to identify potential licensees of the institution's discoveries and negotiate a license with them. If such a license is secured, the institution and the licensing entity share in the license fee in a pre-arranged proportion.

Characteristics:
Commercialization flexibility: Low
Benefit to the institution: Varies, but lower than direct license
Benefit to the investigator: Varies from low to moderate
Administrative burden: Low
Institutional risk control: High
Institutional risk exposure:
Fiduciary liability: Low
Product liability: Moderate

3. **Licensing Through a Related Entity.** Under this model, the institution creates a licensing entity that performs the same set of services as an outside licensing entity, described above, but working only for the institution (or for a small group of affiliated institutions).

Characteristics:
Commercialization flexibility: Low
Benefit to the institution: Varies
Benefit to the investigator: Varies from very low to moderate
Administrative burden: Low for the institution but high for the related entity
Institutional risk control: High
Institutional risk exposure:
Fiduciary liability: Low for the institution but moderate for the related entity
Product liability: Moderately low for the institution and moderate for the related entity

Involvement in the Commercialization Process

The alternative to licensing the rights to commercialize a discovery is the involvement of the institution in the actual commercialization process, either by bringing the product to market itself, or in entering into a joint venture of some sort with one or more commercial enterprises. The specific way this relationship is configured substantially affects the risks and benefits to the institution.

1. **Direct Commercialization.** An institution may develop a discovery and produce it within its own facilities for commercial sale.

Characteristics:
Commercialization flexibility: Very High
Benefit to the institution: Very high
Benefit to the investigator: Varies, but usually high
Administrative burden: Very high
Institutional risk control: High
Institutional risk exposure:
Fiduciary liability: Very high
Product liability: Very high

2. **Commercialization Through a Related Entity.** As an alternative to directly engaging in commercial activity, some institutions have

created related for- or non-profit entities that are granted rights to discoveries and assume the commercialization role.

Characteristics:
Commercialization flexibility: Very high
Benefit to the institution: Very high
Benefit to the investigator: Varies, but usually high
Administrative burden: Low to the institution but very high to the related entity
Institutional risk control: High
Institutional risk exposure:
Fiduciary liability: Low to moderate
Product liability: Moderate

3. **Commercialization Through Spin-Off Companies Controlled by a Related Entity in Cooperation with One or More Commercial Partners.** In other instances, a related entity that is controlled by the institution does not itself engage in commercial activity. Instead, having been granted the rights to a discovery by the institution, the related entity would license those rights to a separate, but controlled, spin-off company. That spin-off company is then capitalized and, usually as a joint venture with a commercial partner, completes development of the discovery and either brings it into the marketplace or sells the developed discovery to the commercial partner for production and marketing.

Characteristics:
Commercialization flexibility: Very high
Benefit to the institution: Very high
Benefit to the investigator: Varies, but usually high
Administrative burden: Low to the institution but high to the related entity
Institutional risk control: High
Institutional risk exposure:
Fiduciary liability: Low
Product liability: Low

While the spin-off entity may be a joint venture or have outside investment, that need not be the case. There are a number of examples of such entities being wholly owned by the institution or its intermediary (or both) with the whole of the earnings going back to the institution, and with the institution exercising

total management control. To the extent the spin-off entity is entirely controlled by the institution, the risk characteristics are altered:

Characteristics:
Commercialization flexibility: Very high
Benefit to the institution: Very high
Benefit to the investigator: Varies, but usually high
Administrative burden: Low to moderate to the institution but high to the related entity
Institutional risk control: High
Institutional risk exposure:
Fiduciary liability: Moderate to high
Product liability: Moderate to high

The models described above are typical of the various structures used by institutions to move discoveries from the campus into the marketplace. The attributes of each are generally valid for the wide range of minor variations that characterize their use among different institutions. It is important to remember, however, that any variation in structure *could* significantly alter the characteristics discussed above. Only after careful review by legal counsel can the actual degree of risk be assessed.

It is also important to recognize that the risk characteristics described in this section deal with primary liability, and do not take into account the use of *risk shifting* techniques, most notably insurance. The use of various forms of insurance (and its close parallel, indemnification) may make acceptable what would otherwise be an unacceptably high level of institutional risk of liability.

In the final analysis, virtually all forms of commercial liability can be insured against. But to do so, both the institution and the insurer need to be able to accurately assess the degree of risk. For the latter, that assessment drives the cost of the insurance; for the former, it allows for a rational decision whether to pay the certainty of a premium (and avoid the risk of loss) or accept the risk of loss (and avoid the cost of the insurance).

Conclusion

The transfer of technology, through the commercialization of discoveries by college and university faculty members, is becoming an inescapable fact of life for an increasing number of institutions. Indeed, it is a practice that should benefit the institution, its faculty and the nation. However, it is also a practice—in whatever form it is carried out—that can pose potentially significant risks to the institution.

Nevertheless, through knowledge, prudent management and the use of the full panoply of risk-control instruments, some risks can be eliminated entirely and all can at least be reduced to manageable levels. Indeed, no category of risk should be so threatening as to preclude the involvement of colleges and universities in the process of moving discoveries from the laboratory into the open marketplace—and in assuring the institution of appropriate benefit from that transfer.

But *every* category of risk needs to be evaluated in the context of how the institution manages its technology transfer program. Even the well-managed programs will inevitably pose certain risks, but they will be reasonable and foreseeable risks, controllable within the capacity of the institution. It is the technology transfer program that exists without careful oversight, and without a clear understanding on the part of its management of the related risks and the ways to control them, that places the institution, its resources and its personnel at risk.

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